

Qualification Unit

This unit forms part of a regulated qualification.

Unit Title: Environmental Principles in Pharmaceutical Technical Services

Unit Reference Number: H/650/7516

Level: Two (2)

Credit Value: Two (2)

Minimum Guided Learning Hours: 16

Learning Outcome (The Learner will):	Assessment Criterion (The Learner can):
1. Know the legislation and guidance relating to environmental principles in Pharmaceutical Technical Services	1.1 Summarise legislation and guidance regarding environmental principles and monitoring
	1.2 Explain the functions of: a) Room classification b) Clear air devices
	1.3 Explain the importance of environmental parameters in the workplace
	1.4 Describe the appropriate methods of contamination prevention
	1.5 Outline the limitations of own role, including when to refer to an appropriate member
2. Be able to carry out environmental checks within the workplace	2.1 Prepare and set-up environmental monitoring equipment
	2.2 Carry out environmental monitoring checks
	2.3 Clean and prepare controlled areas
	2.4 Identify and resolve any discrepancies highlighted during environmental monitoring
	2.5 Refer to an appropriate member of the team when a discrepancy is outside the limits of responsibility

Indicative Content

LO1	<p>AC 1.1 should be assessed holistically with the criteria in unit 1 (Roles, Responsibilities and Professional Development in Pharmaceutical Technical Services). This could include: Standard Operating Procedures (SOP's); COSHH; Good Manufacturing Practice (GMP); Good Clinical Practice (GCP); The Medicines Act 1968; Rules and Guidance for Pharmaceutical Manufacturers and Distributors (The Orange Guide); Human Medicines Regulation 2012; Quality Assurance of Aseptic Preparation Services (QAAPS); Pharmaceutical Quality System (PQS)</p> <p>AC 1.2 could include clean air devices and classifications of areas (e.g. Grade A; Grade B; Grade C; Grade D; Unclassified; Controlled).</p> <p>AC 1.3 should include physical monitoring; biological monitoring; airflow ranges; pressure readings.</p>
LO2	<p>AC 2.1 should include: broth tests; Settle plates; validation kits; air sampling.</p> <p>AC 2.2 should include: air pressures; daily settle plates; weekly settle plates; broth tests; gowning validations; air sampling; contact plates.</p>